EPA Registration Number 84229-31

PROCESSING REQUEST

Reg # 94229-3/ 1	Decision # 505 046
Description: Cond Mon	TO TO THE PARTY OF
	
Eleganica I abol 9. I attan	Non Electronic
Electronic Label & Letter OR	Label & Letter
(see PPLS):	(Scanning required):
☐ Dated:	□ Dated:
Only one label type	should be selected
Other Materials Sent (see ja	icket):
New CSF(s) Dated:	
☑ Other: 10 -5-15	
File this coversheet and attached materials and clipped together, NOT STAPLED. Then	
materials to staff in the Information Service	es Center (ISC) (Room S-4900). If a
jacket is full or only available as an image, bring it down to the (ISC). For further info	
orning it down to the (100). To raidle line	
Reviewer: Bompo Mos	M
Division: RIVIII	
Phone: 305-7269	Date: 10-5-15



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 5, 2015

Ms. Ann M. Tillman Agent for Tide International, USA, Inc. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332

Subject:

Condition of Registration – Storage Stability and Corrosion Characteristics Data

Product Name: Tide Hexazinone Technical EPA Registration Number: 84229-31

Application Date: 4-15-15 Decision Number: 505046

Dear Ms. Tillman:

The Agency has reviewed the study submitted to fulfill the conditional data requirements referred to above, in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act. A copy of the review is enclosed. The study has been classified as acceptable. The conditions of registration are considered fulfilled.

If you have any questions, please contact Banza Djapao at 703-305-7269 or by email at djapao.banza@epa.gov.

Sincerely,

Heather A. Garvie, Product Manager 24 Fungicide Herbicide Branch (7505P)

Office of Pesticide Programs

Lasthold Hume

Enclosure: Product Chemistry review; DP# 427408 dated 9-29-15

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

This Document Contains Confidential Information

DATE OUT:	September 29, 2015
SUBJECT:	STORAGE STABILITY (830.6317) & CORROSION CHARACTERISTICS (830.6320) REVIEW ACCELERATED STUDY []; ONE YEAR STUDY [X]; OVER 1 YEAR STUDY [] MP [] EP [] EUP [X] DP BARCODE No.: 427408 REG. No.: 84229-31 DECISION No.: 505046 MRID No(s): 496160-01 PRODUCT NAME: TIDE HEXAZINONE TECHNICAL COMPANY: TIDE INTERNATIONAL, USA, INC.
FROM:	Linda Mascall / Bruce Kitchens John Struce Kitchens Product Chemistry Team Chemistry, Inerts and Toxicology Assessment Branch (CITAB)/RD (7505P)
то:	Banza Djapao / Heather Garvie, RM 24 Fungicide and Herbicide Branch / RD (7505P)
I. CONCLUS	IONS:
[X] ACCE	E STABILITY (830.6317): EPTABLE CCEPTABLE* RADEABLE*
40CFR158.3	310 DATA REQUIREMENT: [X] SATISFIED [] NOT SATISFIED
[X] ACCE [] UNAC	ON CHARACTERISTICS (830.6320): PTABLE CEPTABLE* ADEABLE*
40CFR158.3	10 DATA REQUIREMENT: [X] SATISFIED [] NOT SATISFIED
* If unaccept	able or upgradeable describe the deficiency and provide recommendations

Comments & Recommendations:

The various parameters tested in the study at the end of storage period (21.0 to 28.2 °C) for the year were not significantly different from the results obtained before storage. The properties of technical compound were not adversely affected by storage at ambient temperature. For corrosion characteristics like "Perforation", "Darkening", "rust at the seam" were not observed on packaging material due to contact with test article.

From the results obtained in the study, it is concluded that *Hexazinone Technical* was found to be stable and did not show any corrosion with packaging material at ambient temperature $(27 \pm 9 \, ^{\circ}\text{C})$ for One year storage.

II. STUDY SUMMARY

A. STUDY CONDUCTED UNDER US GLP/OECD GUIDELINES

[X] Yes [] No

B. PRODUCT INFORMATION

Active ingredient(s): Hexazinone

Label claim(s) Nominal concentration(s) (%): 99.2

Initial concentration(s) of the AI(s) (%) used in the study: 98.58 Lower certified limits (%) based on AI % in the study: 96.2426

C. EXPERIMENTAL PARAMETERS

[emperature: [] Freezer; Room []; Warehouse [X]; 54°C []; Other []
lumidity: Indicate % (if provided)
Duration of study: [X] 1 year; [] over 1 year
ype of container: [] Glass; [] Metal; [X] HDPE; [] Fluorinated HDPE; [] Other
Analysis at intervals: [X] 0 (initial);
X] 3 months; [X] 6 months
] 9 months; [X] 12 months
Over 12 months

D. ANALYTICAL METHOD

Method	DETECTOR
	□ FID (Flame Ionization Detector)
Gas chromatography (GC)	□ ECD (Electron Capture
·	Detector)
	□ N/P (Nitrogen/Phosphorous
	Detector)
	□ Other
	☐ FID (Flame Ionization Detector)
Capillary Gas chromatography (CGC)	☐ ECD (Electron Capture
	Detector)
	□ N/P (Nitrogen/Phosphorous
	Detector)
	□ Other
	$\sqrt{\text{UV/VIS} (\text{nm})} - 254 \text{ (nm)}$
High Pressure Liquid chromatography	☐ RI (Refractive Index)
(HPLC)	□ Other
00 M0 / L 0 M0	Consider
GC-MS / LC-MS	Specify
Other	Specify

E. RESULTS

Active Ingredient Content in Test Article

			T.	Average Active
Storage Period	Sample No.	Actual Conc. of	Active Ingredient	Ingredient
(Months)		test article (ppm)	content (% w/w)	content (% w/w)
0 (Before	1	86.4	98.33	
Storage)	2	90.4	98.82	98.58
3	1	88.0	98.81	
	2	85.2	98.64	98.73
6	1	83.0	98.94	
	2	82.6	99.57	99.25
12	1	86.6	98.65	
	2	84.4	99.60	99.13



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

April 29, 2015

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

PYXIS REGULATORY CONSULTING, INC TIDE INTERNATIONAL, USA, INC. 4110 136TH ST. NW GIG HARBOR, WA 98332

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 16-APR-15. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

PYXIS REGULATORY CONSULTING, INc.

4110 136th St. NW Gig Harbor, WA 98332

Phone: 253-853-7369 Fax: 253-853-5516 www.PyxisRC.com

49616000

April 15, 2015

COURIER DELIVERY

Shaja Joyner (PM 20)
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Dear Ms. Joyner,

RE:

Tide International USA, Inc.

Tide Hexazinone Technical (EPA Reg. No. 84229-31)

Submission of Final Report for Storage Stability and Corrosion Characteristics

On behalf of Tide International USA, Inc., I am submitting the final report from storage stability and corrosion characteristics study with Tide Hexazinone Technical.

The following documents are enclosed:

- 1. Application for Pesticide Registration (EPA Form 8570-1)
- 2. Letter of Authorization
- 3. Product Specific Data (3 copies).

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- 1			
	Volume 1	830.6317,	Karambelkar, N. P. Determination of 1 Year Storage Stability
		830.6320	and Corrosion Characteristics of Hexazinone Technical.

I trust you will find this submission complete. However, please feel free to contact me if you have any questions or need any additional information.

Sincerely,

Ann M. Tillman

Enclosures

Please read instructions	on reverse before compl	eting form.	Form	n Approved. OM	B No. 2070-00	60. Approval expires 2-28-9
\$EPA	Environmenta	United States I Protection DC 20	• •	<u> </u>	pistration endment per	OPP Identifier Number
		Applicati	on for Pesticide - S	Section I		
1. Company/Product Nur 84229-31	mber		2. EPA Product S Joyner	Managar	\ _	Proposed Classification None Restricted
4. Company/Product (Na Tide International USA, I	rne) nc./Tide Hexazinone Techi	nical	PM#	20	L	
5. Name and Address of Title International US c/o Pyxis Regulatory 4110 136th St. NW Gig Harbor, WA 983	SA, Inc. Consulting Inc.	ode)	fb)(i), my prod to:	ouct is similar o	r identical in c	h FIFRA Section 3(c)(3) composition and labeling
		 	Section - II			
Notification - Exp	response to Agency lette		Agence "Me T	rinted labels in re y letter dated oo" Application. - Explain below.	opsonse to	
	port for storage stability					
			Section - III			
1. Material This Product	Will Be Packaged in:					
Child-Resistant Packagin Yes Vio Cartification must	Yes No	No. per	Water Soluble Packagin Yes ✓ No If "Yes" No. Package wgt con		ype of Containe Metal Plastic Glass Paper Other	
be submitted				<u></u>		
3. Location of Net Conte	nts Information Container	4. Size(s) Re	tail Container 5, 10, 20 lbs.	[J] On	of Label Direct Label Labeling accompan	•
6. Manner in Which Labe	is Affixed to Product	✓ Litho	graph [] glued alled	Other		
			Section - IV			
1. Contact Point (Comp	lete items directly below	for identificati	on of individual to be contact	ted, if necessary	, to process the	is applicāticht)
Name Pyxis Regulatory Co			Title Consultant		Telepho	ne No. (Inglude Area Coul)? 853-7369
I certify that the si i scknowledge that both under applica	t any knowlingily false of	Certificanthis form end misleading st	Stion I all attachments thereto are atement may be punishable	true, accurate a by fina or impris	and complete, comment or	6. Date Application (1986)
2. Signature	m Telle		3. Title Consultant			
4. Typed Name Ann M. Tillman			5. Date 4/15/15	<u></u>		

Administrative Materials



Tide International (USA) Inc.

21 Hubble, Irvine, CA 92618, USA. Phone: 949-679-3535 Fax: 949-679-3538

December 28, 2009

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Janelle Kay and Michael Kellogg of Pyxis Regulatory
Consulting, Inc. are authorized to act as agent for Tide International USA, Inc. (EPA Company Number
84229), before the U.S. Environmental Protection Agency, California Department of Pesticide Regulation
Pesticide Registration Branch and other state governmental agencies in all matters regarding our
pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7
U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Der-I Wang, Ph.D.

Vice President

cc: Pyxis Regulatory Consulting, Inc.

Memorandum

Date:

PM 24 ___, Regulatory Manager To:

Information Services Branch, ITRMD From:

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

Fully accepted submission This is a:

partially accepted submission

☐ rejected submission

PROCESSING REQUEST

Reg #84229-31	g #84229-31 Decision #502671				
Description:					
Electronic Label & Letter OR (see PPLS):	Non Electronic Label & Letter (Scanning required):				
☐ Dated: 5-6-15	☐ Dated:				
Only one label type	should be selected				
Other Materials Sent (see ja	acket):				
Other:					
File this coversheet and attached materials and clipped together, NOT STAPLED. Then materials to staff in the Information Service jacket is full or only available as an image, bring it down to the (ISC). For further info	give the jacket with the coversheet and es Center (ISC) (Room S-4900). If a please file materials in a new jacket and				
Reviewer: Erik Kraft	·				
Division: RD					
Phone: 703-308-9358	Date:5-6-15				



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 6, 2015

Nicole Cochran Agent Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332

Subject:

Label Notification per PRN 2007-4 - Revision Container Handling

Product Name: Tide Hexazinone Technical

EPA Registration Number: 84229-31

Application Date: 3-13-15 Decision Number: 502671

77

Dear Ms. Cochran:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 2007-4 and finds that the action requested falls within the scope of PRN-2007-4.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on <u>non-refillable</u> containers. The code may appear either on the label (and can be added by non-notification via PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact Erik Kraft by phone at 703-308-9358, or via email at kraft.erik@epa.gov.

Sincerely,

Heather Garvie, Product Manager 24 Fungicide and Herbicide Branch Registration Division (7505P) Office of Pesticide Programs

Ein My for

Enclosure

NOTIFICATION

84229-31

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

05/06/2015

Tide Hexazinone Technical

[Alternate Brand Name: Tide Hexar Technical]

For Manufacturing Use Only

ACTIVE INGREDIENT:

KEEP OUT OF REACH OF CHILDREN DANGER

	FIRST AID
If in eyes:	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
	Call a poison control center or doctor for treatment advice.
If on skin or	Take off contaminated clothing.
clothing:	Rinse skin immediately with plenty of water for 15-20 minutes.
_	Call a poison control center or doctor for treatment advice.
If swallowed:	Call a poison control center or doctor immediately for treatment advice.
	Have person sip a glass of water if able to swallow.
	Do not induce vomiting unless told to do so by the poison control center or doctor.
	Do not give anything by mouth to an unconscious person.
NOTE TO PH	YSICIAN: Probable mucosal damage may contraindicate the use of
gastric lavage	· · · · · · · · · · · · · · · · · · ·
<u> </u>	HOT LINE NUMBER
	duct container or label with you when calling a poison control center or ng for treatment. You may also contact CHEMTREC at 1-800-424-9300 for

EPA Reg. No 84229-31 EPA Est. No: xxxx

emergency medical treatment information.

Manufactured for: Tide International USA, Inc. 21 Hubble Irvine, CA 92618

Net Weight: XXXX lbs.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Danger. Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wear: protective eyewear (goggles, face shield, or safety glasses), long-sleeved shirt and long pants, socks, shoes, and chemical resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, ocean or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting of authority has been notified in writing prior to discharge. Do not discharge effluent containing this product in sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for use in the manufacture of herbicides for the following uses:

- 1. Terrestrial Non-food Crops: Agricultural fallow/idle land, Christmas tree plantations, industrial areas (outdoor), nonagricultural rights-of-way/fencerows/hedgerows, nonagricultural uncultivated areas/soils, bermudagrass/bahiagrass (non-residential areas only);
- 2. Terrestrial Feed Crops: Agricultural rights-of-way/fencerows/hedgerows, alfalfa, grass forage/fodder/hay, pastures, rangelands,
 - 3. Terrestrial Food and Feed Crops: pineapple, sugarcane
 - 4. Terrestrial Food Crops: blueberry
 - 5. Forestry: conifer release, forest plantings (reforestation programs), forest trees
- 6. Uses for which EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.
- 7. Uses for experimental purposes that are in compliance with EPA registration for the formulated products.

Each formulator is responsible for obtaining EPA registration for their end-use product(s).

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage, disposal, or cleaning of equipment.

Pesticide Storage: Store in original container in a cool, dry place.

Pesticide Disposal: Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Handling:

[Plastic bag]: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Do not burn, unless allowed by state and local ordinances.

[Fiber drum with liner]: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed of in accordance with local, state and federal regulations. When completely empty, offer for recycling if available. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY Warranty and Disclaimer Statement

The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Such risks may arise from weather conditions, soil factors, off-target movement, unconventional farming techniques, the presence of other materials, the manner of use or application, or other unknown factors, all of which are beyond the control of Tide International USA, Inc. ("Tide"), and can cause crop injury, injury to non-target crops or plants, ineffectiveness of the product, or other unintended consequences. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

Tide warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks described above, when used in accordance with the Directions for Use under normal conditions. This warranty does not extend to the use of this product contrary to label instructions or under conditions not reasonably foreseeable to Tide, and is subject to the inherent risks described above.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, TIDE DISCLAIMS ALL OTHER **EXPRESS** IMPLIED, WARRANTIES, OR INCLUDING ANY WARRANTY MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, TIDE, MANUFACTURER, AND SELLER DISCLAIM AND SHALL NOT BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE, HANDLING, APPLICATION, STORAGE, OR DISPOSAL OF THIS PRODUCT OR FOR DAMAGES IN THE NATURE OF PENALTIES, AND THE USER AND BUYER WAIVE ANY RIGHT THAT THEY MAY HAVE TO NO AGENT, REPRESENTATIVE OR EMPLOYEE OF TIDE IS SUCH DAMAGES. AUTHORIZED TO MAKE ANY WARRANTY, GUARANTEE OR REPRESENTATION BEYOND Formatte

THOSE CONTAINED HEREIN OR TO MODIFY THE WARRANTIES CONTAINED HEREIN. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE TOTAL LIABILITY OF TIDE, MANUFACTURER, AND SELLER, SHALL BE LIMITED TO THE PURCHASE PRICE PAID, OR AT TIDE'S ELECTION, THE REPLACEMENT OF THE PRODUCT.

EPA 20150313

Deleted:

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW Gig Harbor, WA 98332

Phone: 253-853-7369 Fax: 253-853-5516 Nicole@PyxisRC.com

March 13, 2015

COURIER DELIVERY

Shaja Joyner (PM 20)
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

RE: Tide International, USA, Inc. – Tide Hexazinone Technical (EPA Reg. No. 84229-31)
Notification of a Revision to the Container Handling Language per PRN 2007-4

Dear Ms. Joyner,

On behalf of Tide International, USA, Inc. please find the enclosed notification of revision to the container handling language per PRN 2007-4 for Tide Hexazinone Technical (EPA Reg. No. 84229-31). Tide is adding container handling instructions for plastic bags.

In support of this notification submission, we submit the following documents:

- 1. Completed Application for Registration (EPA Form 8570-1)
- 2. One (1) copy of the Tide Hexazinone Technical labeling with changes tracked
- 3. One (1) copy of the Tide Hexazinone Technical labeling with changes incorporated
- 4. Certification with Respect to Label Integrity
- 5. One (1) copy of the Tide Hexazinone Technical labeling on CD
- 6. Letter of Authorization

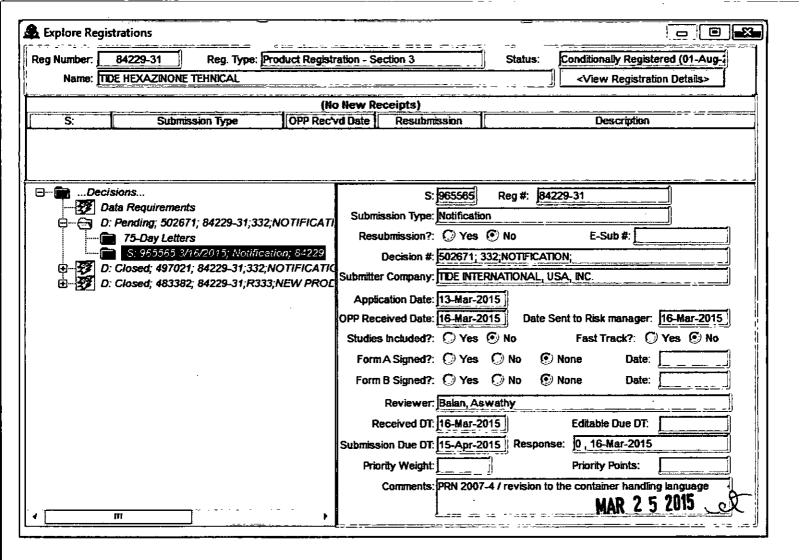
Please feel free to contact me by phone (253) 853-7369 or by email at Nicole@PyxisRC.com if you have any questions or need any additional information.

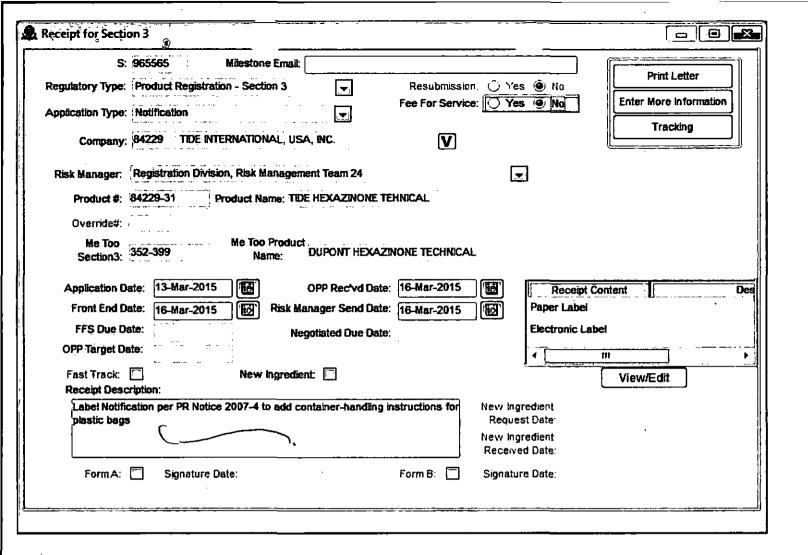
Sincerely,

Nicole Cochran

Enclosures

cc: A. Van Wagner, Tide International, USA, Inc.





\$EPA	Environmenta	inited States Protecti ngton, DC 20	_	псу		✓	Registr Amend Other			P Iden	ntifier Numb	er
		Applicati	on for P	esticio	te - Sec	tion	ı					
1. Company/Product Numbe 84229-31	r				roduct Mar	neger		3.	. Ргоро	ed Cla	ssification	
		·		S. Joyr	ner				√ No	ne [Restri	cted
 Company/Product (Name) Tide International, USA, Inc. 		nnical		PM#		20			_ -			
5. Name and Address of Apa Tide International, USA, c/o Pyxis Regulatory Co 4110 136th St. NW Gia Harbor, WA 98332	Inc. nsulting, Inc.	de)		(b)(i), m to: EPA R	y product	is sin	In accord	ntical in	comp	sition	and labeli	
Check if this	s is a new address				ct Name							
<u> </u>	·		Sect	ion - I	<u>!</u>							
Amendment - Explain Resubmission in resp Notification - Explain	onse to Agency letter	dated		- [] []	Final prints Agency let "Me Too" Other - Exp	ter da Applic	ation.	se to 				
regulations at 40 CFR 156.1 Formula for this product. I use amended label is not consist and I may be subject to enfo	nderstand that it is a vio ent with the requiremen	lation of 18 U. ts of 40 CFR	S.C. Sec. 10 56.10, 156. ections 12 ar	001 to will 140, 156.	fully make at 144, 156.146 IFRA.	ny fals	e statement	to EPA.	I further	unders	stand that if	the
1. Material This Product Wil	Be Packaged In:		0001		•							
Child-Resistant Packaging Yes No * Certification must be submitted	Unit Packaging Yes √ No If "Yes" Unit Packaging wgt.	No. per container			No. per containe	ır	2. Type o	Meta Plast Glass Pape	si s	nlas	ed fiber drum stic bags	n or
3. Location of Net Contents	Information	4. Size(s) Re	tail Contain	967	1	5. Lc	cation of L	abel Dire	otions		_	
✓ Lebel C	Container		7, 55.12, 20		lbs.	[-	On Label On Label	ng accomp	anying pr	oduct		
6. Manner in Which Label Is		✓ Litho Pape Stend	graph glued siled		Othe	or						
				on - 1\	/			-	<u></u>			
1. Contact Point (Complete	items directly below f	or identificeti	on of individ	fuel to be	contacted,	if nec	essary, to p	rocess (this app	lication	n. J	
Name Nicole Cochran			Title Agent					1 '	none No) 853-	_	ide Area Co	ide)
I certify that the state I acknowledge that en both under applicable	y knowlinglly false or		i ail attachr					-	1	Receive	pplication of	
2. Signature			3. Title							•••	• •••	
Mil C	2_		Agent							•	-	

5. Date 3/13/15

Nicole Cochran

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
84229-31	March 13, 2015	084229-31.20150313.Tide Hexazinone Technical label.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Mile Col	March 13, 2015
Signature	Date
Nicole Cochran	
Name (typed)	
Agent	
Title	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 10, 2014

Nicole Cochran
Pyxis Regulatory Consulting, Inc.
4110 136th Street NW
Gig Harbor, WA 98332

Subject:

Label Notification per PRN 98-10 - Add Alternate Brand Name

Product Name: Tide Hexazinone Technical

EPA Registration Number: 84229-31

Application Date: 10-30-14 Decision Number: 497021

Dear Ms. Cochran:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The alternate brand name "Tide Hexar Technical" has been added to the product record.

If you have any questions, you may contact Erik Kraft at 703-308-9358 or via email at Kraft. Erik@epa.gov.

Sincerely,

Shaja Joyner, Product Manager 20 Fungicide and Herbicide Branch Registration Division (7505P)

Ein Mes for

Office of Pesticide Programs

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW Gig Harbor, WA 98332

Phone: 253-853-7369 Fax: 253-853-5516 Nicole@PyxisRC.com

October 30, 2014

COURIER DELIVERY

Kathryn Montague (PM 23)
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

497021

RE: Tide International, U

Tide International, USA, Inc. – Tide Hexazinone Technical (EPA Reg. No. 84229-31)

Notification of an Alternate Brand Name per PRN 98-10

Dear Ms. Montague,

On behalf of Tide International, USA, Inc. please find the enclosed notification of an alternate brand name per PRN 98-10 for Tide Hexazinone Technical (EPA Reg. No. 84229-31). The alternate brand name is "Tide Hexar Technical".

In support of this notification submission, we submit the following documents:

- 1. Completed Application for Registration (EPA Form 8570-1)
- 2. One (1) copy of the Tide Hexar Technical labeling with changes tracked
- 3. One (1) copy of the Tide Hexar Technical labeling with changes incorporated
- 4. Certification with Respect to Label Integrity
- 5. One (1) copy of the Tide Hexar Technical labeling on CD
- 6. Letter of Authorization

Please feel free to contact me by phone (253) 853-7369 or by email at Nicole@PyxisRC.com if you have any questions or need any additional information.

Sincerely,

Nicole Cochran

Mind Corl

Enclosures

cc: A. Van Wagner, Tide Internationals, USA, Inc.

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Please read instructions	on reverse before compl.	∆rm.			Form Appr	oved.	.8 No.	2070-00	80. Approval expires 2-28-9
⊕EPA	United States Environmental Protection Agency Washington, DC 20460			. [A	egistra mendi ther		OPP Identifier Number	
		Application	n for	Pesticio	le - Secti	on I			
Company/Product Num Tide International, U				2. EPA P K. Mon	roduct Mana(tague	ger	-	3. P	roposed Classification
4. Company/Product (Nar Tide International, USA, I	ne) nc. / Tide Hexazinone Teci	hnical		PM#	23	3			
5. Name and Address of Tide International, US c/o Pyxis Regulatory 4110 136th St. NW Gig Harbor, WA 9833	SA, Inc. Consulting, Inc.	ode)	·	(b)(i), m to: EPA R		similar	or ident		n FIFRA Section 3(c)(3) omposition and labeling
·			Se	ction - I			 -		
Amendment - Exp Resubmission in r Notification - Expl	esponse to Agency letter	dated		_ [] _ []	Final printed Agency lette "Me Too" Ap Other - Expla	r dated oplication	n.	• to	
with the provisions of f confidential statement to EPA. I further unde	nate brand name per PF PR Notice 98-10 and EF of formula of this produ	RN 98-10. The PA regulations ct. I understation is not co	e alterna at 40 C nd that i nsistent	ate brand n FR 152.46 it is a violat with the te	, and no othe ion of 18 U.S rms of PR No	er chang S.C. Sec otice 98	ges have 5. 1001 to 1-10 and	been ma willfully 40 CFR	notification is consistent ade to the labeling or the make any false statement 152.46, this product may A.
			Sec	tion - II	1				
1. Material This Product	Will Be Packaged In:		•						
Child-Resistant Packaging Yes No	Unit Packaging Yes ✓ No		Wate	r Soluble Pa Yes No	ıckaging	2.	. Type of	Containe Metal Plastic Glass	
* Certification must be submitted	If "Yes" Unit Packaging wgt	No. per . container	If "Ye Packi	es" age wgt	No. per container			Paper Other (lined fiber drum or (Specify) foil lined plastic bags
3. Location of Net Conte	nts Information	4. Size(s) Re		einer 09, 200 lbs	ì		on of Lat On Label On Labeling		ions ying product
6. Manner in Which Labe	l is Affixed to Product	Lithog Paper Stenc	raph glued iled		Other				
			Sec	tion - I\	/				
1. Contact Point (Compl	ete items directly below	for identification	n of indi	vidual to be	contacted, if	necess	ary, to pr	ocess thi	s application.)
Name Nicole Cochran			Title Agent						ne Nog (Include Area Code) 353-7369
	atements I have made or any knowlinglly false or ble law.		all attac						6. Date Application Received (Stamped)
2. Signature Pinol	Col		3. Title Agent						
4. Typed Name Nicole Cochran			5. Date	10/30/	liy				••••





Tide International USA Inc.

21 Hubble, Irvine, CA 92618 Phone: 949-679-3535 Fax: 949-679-3538

April 8, 2014

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Janelle Kay, Michael Kellogg, Leanne Pruett, and Ann Tillman of Pyxis Regulatory Consulting, Inc. are authorized to act as agent for Tide International USA, Inc. (EPA Company Number 84229), before the U.S. Environmental Protection Agency, California Department of Pesticide Regulation Pesticide Registration Branch and other state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Dennis Prentier

Vice President/General Manager

cc: Pyxis Regulatory Consulting, Inc.



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505P) Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460 EPA Reg. Number: Date of Issuance:

84229-31

08-01-2014

NOTICE OF PESTICIDE:

x Registration

__ Reregistration

(under FIFRA, as amended)

Term of Issuance: conditional

Name of Pesticide Product:

Tide Hexazinone Technical

Name and Address of Registrant (include ZIP Code):

Tide International USA, Inc.

c/o Pyxis Regulatory Consulting, Inc.

4110 136th St. NW

Irvine, CA 92618

21 Hubble

Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

- Submit and/or cite all data required for registration review/reregistration of your product when the Agency requires all registrants of similar products to submit data. You must comply with the Hexazinone DCI ID# GDCI-107201-1036 issued on October 13, 2011. If you have questions or concerns regarding registration review, please contact the Chemical Review Manager, Dana Friedman at 703-347-8827 or email at friedman.dana@epa.gov.
- 2. Make the following label revision(s):
 - a. Revise "EPA Reg. No 84229-" to "EPA Reg. No. 84229-31"
 - b. Assure that the EPA establishment number and net contents are also added to the final printed label.
- 3. Within 18 months of the date on this registration notice, the Storage Stability (830.6317) and Corrosion Characteristics (830.6320) studies must be submitted. They must be conducted in the commercial containers of this product and observations should be made at 0, 3, 6, 9, and 12 month intervals.
- 4. Per 40 CFR 156.10(6), submit one copy of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec.6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. The basic formulation (dated 09/10/2013) is acceptable and will be added to your file. If you have any questions regarding this notice, please contact Beth Benbow of my staff at benbow.bethany@epa.gov.

Signature of Approving Official:

Kathryn V. Montague Project Manager 23 Herbicide Branch

Registration Division (7505P)

Date:

08-01-2014

EPA Form 8570-6

ACCEPTED

08/01/2014

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the posticide registered under EPA Reg. No. 84229–31

Tide Hexazinone Technical For Manufacturing Use Only

ACTIVE INGREDIENT:

KEEP OUT OF REACH OF CHILDREN DANGER

	FIRST AID
If in eyes:	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
lf on skin or clothing:	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
if swallowed:	 Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
NOTE TO BU	
gastric lavage	YSICIAN: Probable mucosal damage may contraindicate the use of

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC at 1-800-424-9300 for emergency medical treatment information.

EPA Reg. No 84229-GR EPA Est. No: xxxx

> Manufactured for: Tide International USA, Inc. 21 Hubble Irvine, CA 92618

Net Weight: XXXX lbs.

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Danger. Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wear: protective eyewear (goggles, face shield, or safety glasses), long-sleeved shirt and long pants, socks, shoes, and chemical resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, ocean or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting of authority has been notified in writing prior to discharge. Do not discharge effluent containing this product in sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for use in the manufacture of herbicides for the following uses:

- 1. Terrestrial Non-food Crops: Agricultural fallow/idle land, Christmas tree plantations, industrial areas (outdoor), nonagricultural rights-of-way/fencerows/hedgerows, nonagricultural uncultivated areas/soils, bermudagrass/bahiagrass (non-residential areas only);
- 2. Terrestrial Feed Crops: Agricultural rights-of-way/fencerows/hedgerows, alfalfa, grass forage/fodder/hay, pastures, rangelands,
 - 3. Terrestrial Food and Feed Crops: pineapple, sugarcane
 - 4. Terrestrial Food Crops: blueberry
 - 5. Forestry: conifer release, forest plantings (reforestation programs), forest trees
- 6. Uses for which EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.
- 7. Uses for experimental purposes that are in compliance with EPA registration for the formulated products.

Each formulator is responsible for obtaining EPA registration for their end-use product(s).

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage, disposal, or cleaning of equipment.

Pesticide Storage: Store in original container in a cool, dry place.

Pesticide Disposal: Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed of in accordance with local, state and federal regulations. When completely empty, offer for recycling if available. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY Warranty and Disclaimer Statement

The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Such risks may arise from weather conditions, soil factors, off-target movement, unconventional farming techniques, the presence of other materials, the manner of use or application, or other unknown factors, all of which are beyond the control of Tide International USA, Inc. ("Tide"), and can cause crop injury, injury to non-target crops or plants, ineffectiveness of the product, or other unintended consequences. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

Tide warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks described above, when used in accordance with the Directions for Use under normal conditions. This warranty does not extend to the use of this product contrary to label instructions or under conditions not reasonably foreseeable to Tide, and is subject to the inherent risks described above.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, TIDE DISCLAIMS ALL OTHER WARRANTIES. **EXPRESS** OR IMPLIED. INCLUDING ANY WARRANTY MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, TIDE, MANUFACTURER, AND SELLER DISCLAIM AND SHALL NOT BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE, HANDLING, APPLICATION, STORAGE, OR DISPOSAL OF THIS PRODUCT OR FOR DAMAGES IN THE NATURE OF PENALTIES, AND THE USER AND BUYER WAIVE ANY RIGHT THAT THEY MAY HAVE TO SUCH DAMAGES. NO AGENT, REPRESENTATIVE OR EMPLOYEE OF TIDE IS AUTHORIZED TO MAKE ANY WARRANTY, GUARANTEE OR REPRESENTATION BEYOND THOSE CONTAINED HEREIN OR TO MODIFY THE WARRANTIES CONTAINED HEREIN. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE TOTAL LIABILITY OF TIDE, MANUFACTURER, AND SELLER. SHALL BE LIMITED TO THE PURCHASE PRICE PAID, OR AT TIDE'S ELECTION, THE REPLACEMENT OF THE PRODUCT.

[EPA approval date]



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

29/APR/2014

MEMORANDUM: Acute Toxicity Data Evaluation Record (DER) for Tide Hexazinone Technical

Subject:

Name of Pesticide Product:

Tide Hexazinone Technical

EPA File Symbol:

84229-GR

DP Barcode:

D415784

Decision No.:

483382

Action Code:

R333

PC Codes:

107201 Hexazinone

From:

Tracy Keigwin, Biologist

Technical Review Branch

Registration Division (7505P)

To:

Bethany Benbow, Team 23

Herbicide Branch

Registration Division (7505P)

Applicant:

Tide International USA Inc.

c/o Pyxis Regulatory Consulting, Inc.

4110 136th St. NW

Gig Harbor, WA 98332

FORMULATION FROM LABEL:

Active Ingredient(s):

% by wt.

Hexazinone

99.2

Other Ingredient(s):

0.8

Total:

100.0%

ACTION REQUESTED: The Risk Manager requests a review of the acute toxicity data submitted in support of EPA File Symbol 84229-GR, Tide Hexazinone Technical.

BACKGROUND: Tide International USA, Inc. has submitted an application for the registration of EPA File Symbol 84229-GR, Tide Hexazinone Technical. They have claimed similarity to DuPont Hexazinone Technical, EPA Reg. No. 352-399 and have additionally submitted product specific acute toxicity data. The MRIDs for these studies are as follows: 49219916 (870.1100), 49219917 (870.1200), 49219918 (870.1300), 49219919 (870.2400), 49219920 (870.2500) and 49219921 (870.2600). The product label states that Tide Hexazinone Technical is for the manufacture of herbicides for listed areas.

GLP: All studies were conducted in accordance with GLP.

DEFICIENCIES: Problems with primary eye and dermal sensitization studies. See #2 and #3, below.

COMMENTS AND RECOMMENDATIONS:

1) While the registrant has claimed similarity to EPA Reg. No. 352-399, we have determined the acute toxicity profile from the product specific acute toxicity data submitted by the registrant. Only 4 of the 6 acute toxicity studies are acceptable. The primary eye irritation and dermal sensitization studies are both classified as supplementary (see below). At present, the acute toxicity profile for EPA File Symbol 84229-GR is as follows:

acute oral toxicity	Ш	Acceptable	MRID 49219916
acute dermal toxicity	181	Acceptable	MRID 49219917
acute inhalation toxicity	IV	Acceptable	MRID 49219918
primary eye irritation*	ſ	Supplementary	MRID 49219919
primary skin irritation	IV	Acceptable	MRID 49219920
dermal sensitization*	YES	Supplementary	MRID 49219921

^{*}Primary eye irritation and dermal sensitization studies are Supplementary

- 2) The primary eye irritation study (MRID 49219919) is classified as <u>Supplementary</u>. The study states that "...treated and untreated eyes were washed at 1 hour following instillation ..." HED Test Guidelines 870.2400 state that "the eyes of the test animals should not be washed out for <u>24 hours</u> following instillation of the test substance." We can accept this study for regulatory purposes provided the registrant accepts a Category I rating for primary eye irritation. Alternatively the registrant may repeat the study without the eyewash or cite a new study (with MRID number).
- 3) The dermal sensitization study is <u>Supplementary</u>. The same vehicle should have been used for both the induction and challenge applications. In addition, the induction application chosen is supposed to be the highest concentration tested causing mild irritation. The selected vehicle(s) limited the highest concentration tested to 40% and no dermal response of any kind was observed in the pilot study. A different vehicle that allowed a higher concentration should have been chosen. It is difficult to determine if the lack of a dermal response at induction and challenge is due to the low concentration of test substance or if the product truly isn't a dermal sensitizer. We will accept this study for regulatory purposes provided the registrant accept dermal sensitization

labeling for this product. Alternatively the registrant may repeat the study or cite a new study (with MRID number).

- 4) The Basic CSF (dated September 10, 2013) must be approved by the product chemistry team before this action can be finalized.
- 3) The Precautionary and first aid statements for this product are as follows:

PRODUCT ID #:

84229-GR (84229-31)

PRODUCT NAME:

Tide Hexazinone Technical

PRECAUTIONARY STATEMENTS

SIGNAL WORD: DANGER

Hazards to Humans and Domestic Animals:

Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Wear: protective eyewear (goggles, face shield, or safety glasses), long-sleeved shirt and long pants, socks, shoes, and chemical resistant gloves.

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

First Aid:

If in eyes:

- -Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- -Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- -Call a poison control center or doctor for treatment advice.

If on skin:

- -Take off contaminated clothing.
- -Rinse skin immediately with plenty of water for 15-20 minutes.
- -Call a poison control center or doctor for treatment advice.

If swallowed:

- -Call a poison control center or doctor immediately for treatment advice.
- -Have person sip a glass of water if able to swallow.
- -Do not induce vomiting unless told to by a poison control center or doctor.
- -Do not give anything to an unconscious person.

Note to PM/CRM/Registrant: The proposed label must contain a "Note to Physician" which addresses the Category I Primary eye irritation. It must contain the following statement:

"Probable mucosal damage may contraindicate the use of gastric lavage"

In addition, the registrant may include the following information:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Reviewer: Tracy Keigwin Risk Manager (EPA): 23

Date: April 29, 2014

The following table is the Acute Toxicity Data Evaluation Record (DER) for the six studies submitted for the proposed product, EPA File Symbol 84229-GR:

1. **DP BARCODE**: 483382

2. PC CODES: 107201 Hexazinone

3. CURRENT DATE: April 29, 2014

4. TEST MATERIAL: Hexazinone Technical (Purity: 98.5% Hexazinone; Batch Number

20100119-109; White crystalline powder)							
Study/Species/Lab	MRID	Results	Тох	Core			
Study # /Date			Cat	Grade			
Acute oral toxicity / rat	49219916	LD ₅₀ Females = 1554 mg/kg	111	A			
Intox/(Maharashtra, India)		bw. 1280 mg/kg bw and					
Study number 10701/		1690 mg/kg bw					
February 22, 2011		concentrations tested. All					
OCSPP 870.1100; OECD 425		(3/3) survived the 1280					
		mg/kg dose. Animals at this					
		dose level exhibited tremors					
		from the 1 hour through the					
		24 hour observation. No		1			
		gross abnormalities were					
		observed at necropsy. Both					
		animals at the 1690 mg/kg					
		concentration were found					
		dead within 2-4 days					
		following dosing. Clinical					
		observations prior to death					
		included tremors, ataxia, and					
		convulsions from 30 minutes		}			
		following dosing until death.		1			
		No gross abnormalities were	İ				
		observed in the decedents at					
		this dose level at necropsy.					
Acute dermal toxicity / rat	49219917	LD ₅₀ > 2000 mg/kg bw (both	111	A			
Intox/(Maharashtra, India)		sexes and combined). All rats		'`			
Study number 10702/		survived. No clinical					
February 22, 2011		abnormalities were observed.					
OCSPP 870.1200; OECD 402		No gross abnormalities were					
		observed at necropsy.					
Acute inhalation toxicity / rat	49219918	LC ₅₀ > 2.63 mg/L (Nose-only,	IV	Α			
Intox/(Maharashtra, India)		gravimetric; both sexes and					

[a.]	<u> </u>	1, 1, 5, 1, 1,		
Study number 10703/	,	combined). Five males and 5		
February 22, 2011		females tested. Mean MMAD		
OCSPP 870.1300; OECD 403	ľ	and GSD: 1.50 μm and 2.86,		
·		respectively. All rats		
		survived. All exhibited		
		hypoactivity and ruffled		
		appearance following		
		exposure, resolving within 2		
		days. No gross abnormalities		
		were observed at necropsy.		
Primary eye irritation / rabbit	49219919	This study is Supplementary	1	S
Intox/(Maharashtra, India)		and will be classified as		
Study number 10705/		Category I for regulatory		
February 22, 2011		purposes. Treated and		
OCSPP 870.2400; OECD 405		untreated eyes were rinsed 1		
		hour after test substance		
		instillation. No corneal	•	
		opacity or iritis was observed		
		during the study. All animals		
		(3/3) exhibited grade 1		
		redness and/or chemosis (not		!
		•		
		a positive response) from the		
		1 hour observation through		
·		the day 7 observation. One		
		animal (1/3) exhibited grade		
		2 redness (a positive		
		response) at the day 14		1
		observation. All scores "0" by		
		the day 21 observation.		
Primary dermal irritation / rabbit	49219920	PDI = 0.0 (non-irritating). No	IV	Α
Intox/(Maharashtra, India)		erythema or edema was		
Study number 10704/		observed at 1, 24, 48 and 72		
February 22, 2011		hours after patch removal.		
OCSPP 870.2500; OECD 404				
Dermal sensitization /Guinea Pig	49219921	This study is Supplementary	YES	S
Intox/(Maharashtra, India)		and classified as a Sensitizer		
Study number 10706/		for regulatory purposes.		
February 22, 2011		Different vehicles were used		
OCSPP 870.2600; OECD 406		for induction and challenge		
	1	applications. Selected test		
		concentrations were not high		
		enough.		,
		Tested using Buehler method.		

	20 test animals/10 controls. Concentrations selected for the induction and challenge were 40% w/v concentration of test article in 80% ethanol/water and 40% w/v concentration of test article in acetone. Following challenge, no dermal reactions were seen on any of the treated or naïve control animals at either time point.
,	

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: 415782, 415783; FILE SYMBOL No.: 84229-GR; PRODUCT NAME: Tide Hexazinone Technical; DECISION No.: 483382; PC Code(s): 107201; ACTION CODE: R333; FOOD Use: Yes

DATE:

April 17, 2014

SUBJECT:

Product Chemistry Review of "Tide Hexazinone Technical"

FROM:

Shyam Mathur, Ph.D

Product Chemistry Team Leader

Technical Review Branch/RD (7505P)

TO:

Bethany Benbow / Kathryn Montague, RM 23

Herbicide Branch / RD (7505P)"

REGISTRANT: Tide International, USA, Incorporation

USE: Herbicide

FOOD USE: Yes [X] No []

MRID Numbers: 492199-01 to 492199-15

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*Manufacturing process information may be entitled to confidential

DP BARCODE No.: 415782, 415783; FILE SYMBOL No.: 84229-GR; PRODUCT NAME: Tide Hexazinone Technical; DECISION No.: 483382; PC Code(s): 107201; ACTION CODE: R333; FOOD Use: Yes

INTRODUCTION:

The registrant has submitted an application for the registration of the new product Tide Hexazinone technical. The registrant has submitted a CSF for basic formulation (dated September 10, 2013) and the supporting product chemistry data (group A & group B) with MRID Nos. MRID Nos. 492199-01 to -15.

of the impurities present in the technical is considered of tox concern. The Tide Hexazinone technical is produced by the registrant has claimed that the proposed technical is substantially similar to the registered product with Reg. No. 352-399. TRB has been asked to evaluate and determine the acceptability of the proposed basic CSF (dated 09-10-2013) and the supporting product chemistry data and also determine similarity to the cited product.

SUMMARY OF FINDINGS:

- 1. The findings for Group A guideline data were as follows:
 - 830.1550 (product identity & composition): The registrant has submitted a CSF for basic formulation (dated 09-10-2013). The product chemistry data corresponding to this guideline submitted on the CSF satisfy the data requirements of 40CFR§158.320. The nominal concentration 99.2% for Al concurs with the product label claim nominal concentration of 99.2% [MRID 492199-01].
- 830.1600 (description of materials used to produce the product): The product chemistry data submitted corresponding to this guideline satisfy the data requirements of 40CFR§ 158.325. The registrant has submitted the MSDS's for all the starting materials used to produce the hexazinone technical [MRID No. 492199-01].
- 830.1670 (discussion on the formation of impurities): The product chemistry data submitted corresponding to this guideline satisfy the data requirements for 40CFR§158.340. The registrant has listed impurities (in the proposed basic CSF 09-10-2013) which were identified and detected at during the five batch analysis including the impurity marked as [Impurity I] in the CSF was not detected at the concentrations of >0.1% during the five batches analyzed, however, this impurity is highly likely to be present in larger scale batches, a nominal concentration of its proposed in the basic CSF. The registrant has provided mechanism of the formation of these impurities. The registrant has reported impurity of tox concern in the Tide Hexazinone technical [MRID No. 492199-01].

DP BARCODE No.: 415782, 415783; FILE SYMBOL No.: 84229-GR; PRODUCT NAME: <u>Tide</u> Hexazinone Technical; DECISION No.: 483382; PC Code(s): 107201; ACTION CODE: R333; FOOD Use: Yes

- 830.1700 (preliminary analysis): The product chemistry data submitted corresponding to this guideline to support the claims on the CSF satisfy the data requirements of 40CFR§158.345. The five lots of hexazinone technical were analyzed to determine the concentration of the active ingredient hexazinone and the associated impurities. The AI and the Impurity I were determined by using HPLC-UV (210 nm) with internal standard quantification method. The impurity of tox concern was estimated by GC-FID using external standard quantification technique. The structures of the active ingredient and the impurities were confirmed by ¹HNMR, IR, UV and HPLC-MS methods. The analytical methods have been validated for linearity, accuracy and precision [MRID No. 492199-02].
- 830.1750 (certified limits): The product chemistry data submitted corresponding to this guideline satisfy the requirements of 40CFR§158.350. The certified limits for the active ingredient are based on the standard certified limits. The proposed certified limits for the identified impurities are based on the five batch analysis results [MRID No. 492199-02].
- 830.1800 (enforcement analytical method): The product chemistry data submitted corresponding to this guideline satisfy the requirements of 40CFR§158.355. The content of the active ingredient was determined by using HPLC-UV internal standard technique. The analytical method was validated for precision, accuracy and linearity [MRID No. 491407-02].
- 2. The 830 series group B guideline data (physical-chemical properties) submitted satisfy the data requirements of 40CFR§158.310(e) [MRID No. 492199-03 to 492199-15].

DP BARCODE No.: 415782, 415783; FILE SYMBOL No.: 84229-GR; PRODUCT NAME: <u>Tide Hexazinone Technical</u>; DECISION No.: 483382; PC Code(s): 107201; ACTION CODE: R333; FOOD Use: <u>Yes</u>

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for proposed Tide Hexazinone Technical (produced by to support the proposed basic CSF and has concluded that:

- 1. The product chemistry data submitted for guideline 830 Series group A are acceptable.
- 2. The proposed CSF for basic formulation (dated 09-10-2013) is acceptable. The nominal concentration of 99.2% concurs with the product label claim nominal concentration of 99.2%.
- 3. The product chemistry data submitted for guideline 830 Series group B are acceptable. The registrant has informed that studies for the guidelines 830.6317 (storage stability) and 830.6320 (corrosion characteristics) have been initiated and the results will be submitted on completion of studies.
- 4. The proposed product with File Symbol No. 84229-GR was determined not to be substantially similar to the cited product with Reg. No. 352-399 from the product chemistry point of view. The impurity profile of the proposed and cited product is significantly different. The proposed product is more pure and has lesser impurities as compared to cited product.

DP BARCODE No.: 415782, 415783; FILE SYMBOL No.: 84229-GR; PRODUCT NAME: <u>Tide Hexazinone Technical</u>; DECISION No.: 483382; PC Code(s): 107201; ACTION CODE: R333; FOOD Use: Yes

830.1550. Product identity & composition: (MRID No. 492199-01)

Common Name: Hexazinone

CAS name: 3-cyclohexyl-6-(dimethylamino)-1-methyl-1, 3, 5-triazine-2, 4-(1H, 3H)-dione

IUPAC Name: 3-cyclohexyl-6-(dimethylamino)-1-methyl-1, 3, 5-triazine-2, 4-dione

CAS No.: 51235-04-2

Molecular formula: C₁₂H₂₀N₄O₂

Molecular weight: 252.3

Structural Formula:

HEXAZINONE

DP BARCODE No.: 415782, 415783; FILE SYMBOL No.: 84229-GR; PRODUCT NAME: Tide Hexazinone Technical; DECISION No.: 483382; PC Code(s): 107201; ACTION CODE: R333; FOOD Use: Yes

Group A Data

GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	492199-01	Α	Submitted a basic CSF (dated 09-10-13) with NC of 99.2% for the AI.
830.1600	Description of materials used to produce the product	492199-01	Α	Submitted the MSDS's for all the starting materials used in the synthesis of Tide Hexazinone technical at the site located at
				The hexazinone technical was produced in
830.1620	Description of production process		A	to obtain hexazinone technical grade AI (99.2%). The manufacturing process has been described in detail. The quality assurance procedures adopted in each step of the process have beer included.
830.1670	Discussion of formation of impurities		A	Impurities discussed and identified. The discussions on the mechanisms of the formation of all impurities listed on the CSF have been provided. Impurities have been listed in the CSF. The registrant did repo one well known impurity of tox concern in hexazinone technical.
830.1700	Preliminary analysis	492199-02	A	The five batch analysis of the hexazinone technical was conducted to determine the contents of the active ingredient and the impurities. HPLC-UV method was used for the determination of the AI & impurities contents. One of the impurities was identified by using GC-FID with external standard quantitation method. The identities of the impurities & and active ingredient were confirmed by HNMR, IR, UV and GC-MS. The analytical methods were validated for linearity, accuracy, precision LOQ and LOD.
830.1750	Certified limits	492199-01	A	The proposed limits for the AI are based on the standard limits whereas the certified limits for the impurities are proposed on the preliminary analysis basis.
830.1800	Enforcement analytical method	492199-01 492199-03	Α	The HPLC-UV (210 nm) with internal standard method was used for the determination of the Al contents. The method was validated for precision, linearity and accuracy.

DP BARCODE No.: 415782, 415783; FILE SYMBOL No.: 84229-GR; PRODUCT NAME: Tide Hexazinone Technical; DECISION No.: 483382; PC Code(s): 107201; ACTION CODE: R333; FOOD Use: Yes

830 Series Subgroup B (Physical-Chemical properties)

GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	492199-04	Α	White
830.6303	Physical state	492199-05	Α	Solid (crystalline)
830.6304	Odor	492199-06	Α	Pleasant mild odor
830.6313	Stability to normal and elevated temperatures, metals, and metal ions		Α	Stable to metals like iron filings & lead and the metal ions like ferric citrate and lead acetate for two weeks at 54°C
830.6314	Oxidation/reduction: chemical incompatibility	492199-08	A	Test substance was found to be compatible with water, ammonium dihydrogen phosphate, potassium dichromate, potassium permanganate, hydrogen peroxide, iron filings, kerosene and gasoline.
830.6315	Flammability	492199-15	Α	Waiver request
830.6316	Explodability	M # N M	Α	Waiver request
830.6317	Storage stability	H H A A	N	Waiver request denied
830.6319	Miscibility	a 4 4 a	Α	Waiver request
830.6320	Corrosion characteristics	p 11 p 21	N	Waiver request denied
830.7000	рН	492199-09	Α	7.55 at 24.8°C (1% w/v suspension)
830.7050	UV/Visible absorption	492199-10	Α	See Note 1
830.7100	Viscosity	492199-15	Α	Waiver request
830.7200	Melting point	492199-11	Α	Range = 113.6 - 116.8°C
830.7220	Boiling point	492199-15	w	Waiver request
830.7300	Density	492199-12	Α	1.2615 g/ml at 20°C (pycnometer method)
830.7370	Dissociation constants in water (DC)	492199-15	Α	pK _a = 2.2 (25°C); Literature Cited: Tomlin, "The Pesticide manual" 13 th Edition, p539, BCPC Publication, Hampshire 2003
830.7550	Partition coefficient	492199-15	A	Log P = 1.2 (pH, 7) Literature Cited: Tomlin, "The Pesticide manual" 13 th Edition, p539, BCPC Publication, Hampshire 2003
830.7840	Water solubility:	492199-13	Α	34.34 g/L at 25°C (pH=6.5)
830.7950	Vapor pressure	492199-15	Α	0.03 mPa (25°C); Literature Cited: Tomlin, "The Pesticide manual" 13 th Edition, p539, BCPC Publication, Hampshire 2003

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Upgrade (additional information required)

DP BARCODE No.: 415782, 415783; FILE SYMBOL No.: 84229-GR; PRODUCT NAME: Tide Hexazinone Technical; DECISION No.: 483382; PC Code(s): 107201; ACTION CODE: R333; FOOD

Use: Yes

Note 1: 830.7050 (UV-VIS) [MRID No. 492199-10]

, bН	Maximum wavelength (nm)	Molar Absorptivity (Lmol ⁻¹ cm ⁻¹)
1	228.55	12862
2	245.75	15302
7	246.40	17436
10	246.45	17612
11	246.45	17224

Solubility in Organic solvents at 25°C in g/L (MRID No. 492199-14)

Acetone = >250 N-heptane = <10 p-Xylene = 67 to 80 1, 2-dichloroethane = > 250 Methanol = >250 Ethyl acetate = 133 to 160 DP BARCODE No.: 415782, 415783; FILE SYMBOL No.: 84229-GR; PRODUCT NAME: <u>Tide</u> Hexazinone Technical; DECISION No.: 483382; PC Code(s): 107201; ACTION CODE: R333; FOOD Use: Yes

CONFIDENTIAL APPENDIX

830.1600 (description of materials used to produce the product) (MRID No. 492199-01)

The registrant provided the MSDS's for the following raw chemicals used in the synthesis of hexazinone technical:

830.1620 (description of production process)

(MRID No. 492199-01)

DP BARCODE No.: 415782, 415783; FILE SYMBOL No.: 84229-GR; PRODUCT NAME: Tide Hexazinone Technical; DECISION No.: 483382; PC Code(s): 107201; ACTION CODE: R333; FOOD

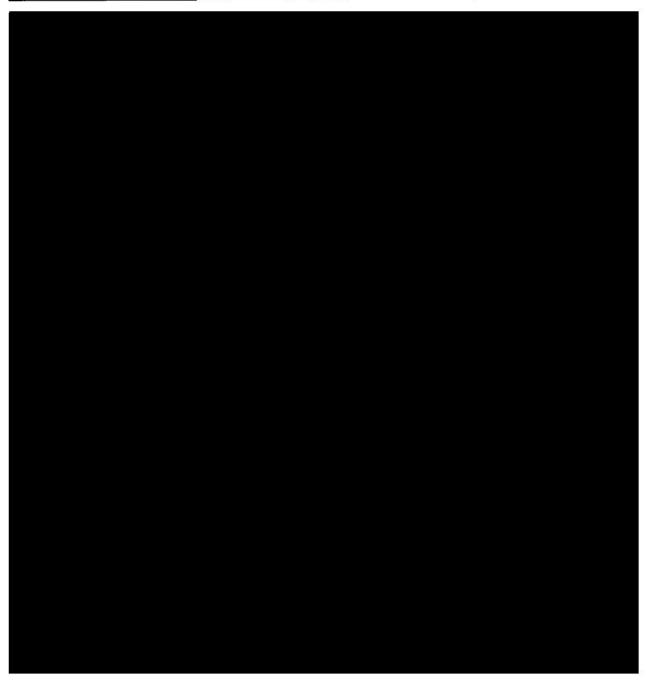
Use: Yes

CONFIDENTIAL APPENDIX

DP BARCODE No.: 415782, 415783; FILE SYMBOL No.: 84229-GR; PRODUCT NAME: <u>Tide</u> Hexazinone Technical; DECISION No.: 483382; PC Code(s): 107201; ACTION CODE: R333; FOOD Use: <u>Yes</u>

CONFIDENTIAL APPENDIX

830.1670 (discussion on the formation of impurities) (MRID No. 492199-01)



DP BARCODE No.: 415782, 415783; FILE SYMBOL No.: 84229-GR; PRODUCT NAME: Tide Hexazinone Technical; DECISION No.: 483382; PC Code(s): 107201; ACTION CODE: R333; FOOD

Use: Yes

CONFIDENTIAL APPENDIX



DP BARCODE No.: 415782, 415783; FILE SYMBOL No.: 84229-GR; PRODUCT NAME: Tide Hexazinone Technical; DECISION No.: 483382; PC Code(s): 107201; ACTION CODE: R333; FOOD

Use: Yes

CONFIDENTIAL APPENDIX

830.1700 (preliminary analysis) [MRID No. 492199-02 & 492199-03]

DP BARCODE No.: 415782, 415783; FILE SYMBOL No.: 84229-GR; PRODUCT NAME: Tide Hexazinone Technical; DECISION No.: 483382; PC Code(s): 107201; ACTION CODE: R333; FOOD Use: Yes

CONFIDENTIAL APPENDIX







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D415782, D415783,; FILE SYMBOL No.: 84229-GR (screen); PRODUCT NAME: Tide

Hexazinone Technical; DECISION No.: 483382; PC Code(s): 107101; ACTION CODE: R333;

FOOD Use: Yes

DATE OUT: November 8, 2013

SUBJECT: Completeness check for TGAI/MUP

Product Name: Tide Hexazinone Technical

FROM: Shyam Mathur,

Product Chemistry Team Leader

Technical Review Branch/RD (7505P)

TO: Bethany Benbow / Kathryn Montague, PM 23

Herbicide Branch / RD (7505P)

Company Name: Tide International USA Incorporation

Formulation Type: Fungicide

Active Ingredient: Hexazinone Technical (99.2%)

MRID Nos.: 492199-01 to 492199-15

Results of completeness check screen

File No./ Reg. No	Product Name	Group A Data Submitted			B Data mitted	CSF	CSF	
		Yes	No	Yes	No	Yes	No	
84229-GR	Tide Hexazinone Technical	+		+		+ Basic 09-10-13		+

CONCLUSION:

Group A: All data submitted

Group B: All data submitted.

CSF: Basic CSF (dated 09-10-2013) submitted. [Production site:

Product label: Submitted

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW Gig Harbor, WA 98332

Phone: 253-853-7369 Fax: 253-853-5516 www.PyxisRC.com

September 19, 2013

OVERNIGHT DELIVERY

Kathryn V. Montague (PM 23)
Document Processing Desk (**REGFEE**)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Dear Ms. Montague,

RE: Tide International USA, Inc.

Tide Hexazinone Technical (EPA Reg. No. 84229-

Application for New Pesticide Registration

PRIA Category R333

On behalf of Tide International USA, Inc., we are submitting an application for registration of Tide Hexazinone Technical. This application for registration is linked to a secondary application (Tide Hexazinone 75 WDG). In support of this application, we submit the following documents:

- 1. Application for a New Pesticide Registration (EPA Form 8570-1)
- 2. Confidential Statement of Formula (EPA Form 8570-4) for Basic Formulation
- 3. Three (3) Copies of the Proposed Labeling
- 4. A CD containing an electronic version of the label
- 5. Certification with Respect to Label Integrity
- 6. Certification with Respect to Citation of Data (EPA Form 8570-34)
- 7. Agency Internal Use Copy of the Data Matrix
- 8. Public File Copy of the Data Matrix
- 9. Copy of PRIA payment
- 10. Letter of Authorization
- 11. Product Specific Data (3 copies of each report)

49219901	Volume 1	830.1550, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800	Tillman, A.M. and Z. Xiangfei. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, Certified Limits and Enforcement Analytical Method for Tide Hexazinone Technical. Contains Confidential Business Information
49219902	Volume 2	830.1700, 830.1800	Tillman, A. M. Compilation Report: 5-Batch Analysis of Hexazinone 98% Tech and Validation of Analytical Methods, Determination of IR, UV/VIS-Absorption and Mass-Spectra. Contains Confidential Business Information
49219903	Volume 3	830.1800	Marne, S. K. Validation of Analytical Method for Hexazinone.
49219904	Volume 4	830.6302	Waghade, D. B. Determination of Colour of Hexazinone
49219905	Volume 5	830.6303	Waghade, D. B. Determination of Physical State of Hexazinone Technical.
49219906	Volume 6	830.6304	Waghade, D. B. Determination of Odour of Hexazinone Technical.

49219907	Volume 7	830.6313	Karambelkar, N. P. Determination of Storage Stability of Hexazinone Technical to Normal and Elevated Temperature, Metals and Metal Ions.
49219908	Volume 8	830.6314	Karambelkar, N. P. Determination of Oxidizing/Reducing Properties of Hexazinone Technical.
49219909	Volume 9	830.7000	Waghade, D. B. Determination of pH of Hexazinone Technical.
49219910	Volume 10	830.7050	Marne, S. K. Determination of UV-Visible Spectrum of Hexazinone Technical.
49219911	Volume	830.7200	Marne, S. K. Determination of Melting Point/Melting Range of Hexazinone Technical.
49219912	Volume 12	830.7300	Waghade, D. B. Determination of Density of Hexazinone Technical.
49219913	Volume 13	830.7840	Karambelkar, N. P. Determination of Solubility of Hexazinone Technical in Water.
49219914	Volume 14	830.7840	Karambelkar, N. P. Determination of Solubility of Hexazinone Technical in Organic Solvents.
49219915	Volume 15	830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7100, 830.7220 830.7370, 830.7520, 830.7550-7570, 830.7950	Tillman, A. M. Tide Hexazinone Technical: Physical and Chemical Properties and Waiver Requests.
49219916	Volume 16	OECD 425	Dhokale, C. S. Acute Oral Toxicity Study of Hexazinone Technical in Rat.
49219917	Volume 17	OECD 402	Dhokale, C. S. Acute Dermal Toxicity Study of Hexazinone Technical in Rat.
49219918	Volume 18	OECD 403	Patil, J. J. Acute Inhalation Toxicity Study of Hexazinone Technical in Rat.
49219919	Volume 19	OECD 405	Kale, M. B. Acute Eye Irritation/Corrosion Test of Hexazinone Technical in Rabbit.
49219920	Volume 20	OECD 404	Kale, M. B. Acute Dermal Irritation/Corrosion Test of Hexazinone Technical in Rabbit.
49219921	Volume 21	OECD 406	Pachpute, P. R. Skin Sensitization Study (Buehler Test) of Hexazinone Technical in Guinea Pigs.

Tide International USA, Inc. is using the cite-all method of data support. As per EPA's interpretations of 40 CFR Parts 152.86(b)(2)(i) and 152.93(b)(2)(i), Tide International USA, Inc. submitted notices of intent to apply and offers to pay to all companies on the April 8, 2013 Data Submitter's List. This action falls under PRIA category R333 (52: New manufacturing-use product). The fee for this action is \$17,993 and has been paid.

Please contact me ((253) 853-7369, Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,

Ann M. Tillman



TIDE INTERNATIONAL USA INC.

21 HUBBLE, IRVINE, CA 92618, USA • Tel: 1-949-679-3535 • Fax: 1-949-679-3538

August 4, 2008

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agents for Tide International USA, Inc. (EPA Company Number 84229), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Der-I Wang,Ph.D Vice President

cc: Pyxis Regulatory Consulting, Inc.

Tide USA Pyxis authorization letter 8-4-08.doc.

Please read instructions on re	verse before completi	na form.	نظام المساحد ا	Form Approved	OMB No. 2070	-0080. An	provel empires 2-28-95
≎EPA	Environmental	ited States Protectio gton, DC 2046	—	7	Registration Amendment Other	••	Identifier Number
		pplication	n for Pesticide	- Section	1		
1. Company/Product Number 84229-			2. EPA Pro K. Monta	duct Meneger gue		3. Proposed	Classification
4. Company/Product (Name) Tide International USA, Inc	./ Tide Hexazinone T	'echnical	PM#	23			Nesuncted
5. Name and Address of Appl Tide International USA, Inc. c/o Pyxis Regulatory Consult 4110 136th St. NW Gig Harbor, WA 98332		le)		oroduct is sim 1. No. 352-39 DuPoi	ilar or identical	in composi	Section 3(c)(3) tion and labeling
			Section - II				
Amendment - Explain I Resubmission in responsion - Explain b Notification - Explain b Explanation: Use additional This application falls under to the secondary application	elow. I page(s) if necessary Category R333 (52: I	. (For section	I and Section II.)	gency letter dat de Too" Applica ther - Explain be	ation. slow.	paid. This	application is linked
			Section - III		 		
1. Material This Product Will (Re Packaged In:		0000011 111				
Child-Resistant Packaging Yes No Cartification must be submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt.	No. per container	Water Soluble Pack Yes No If "Yes" Package wgt	eging No. per container	Pla Gl	teiner etal estic eas per per her (Specify	lined fiber drum or foil lined plastic bags
3. Location of Net Contents In	nformation	4. Size(s) Rote	il Container	5. Lo	cation of Label D	irections	
✓ Label Co	entainer	33.07, 44.	09, 200 lbs (15, 25,	90.72	On Label On Labeling acco	mpanying produ	uct
6. Manner in Which Label is /	Affixed to Product	Lithogr Paper 1 Stencil	aph plued ed	Other			
			Section - IV				
1. Comect Point (Complete i	tems directly below fo	r identification	n of individual to be o	ontected, if nec	essary, to proces	s this epplic	ation.
Neme Ann Tillman			Title Agent	- <u></u> -	1	s e hone No. (5 3) 853- 73	Include Area Code)
Certification I certify that the statements I have made on this form and all attachments thereto ar I acknowledge that any knowlingly false or misleading statement may be punishable both under applicable (aw.					urste end comple imprisonment or		rte Application scolved ** (Stamped)
2. Signature Aun	h weller		Agent				
4. Typed Name Ann Tillman		1	5. Date 9/19	1/13			

EPA Form 8670-1 (Rev. 3-94) Previous editions are obsolete.



Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.

Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.								
Certification with Respect t	to Citation of I	Data						
Applicant's/Registrant's Name, Address, and Telephone Number Tide International USA, Inc. c/o Pyxis Regulatory Consulting 4110 136th St. NW Gig Harbor, WA	98332 253-853	EPA Registration Number/File Symbol 84229-						
Active Ingredient(s) and/or representative test compound(s) Hexazinone	_	Date 9/19/13						
General Use Pattem(s) (list all those claimed for this product using 40 CFR Part 158) TGAI		Product Name Tide Hexazinone Technical						
	NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).							
I am responding to a Data-Call-In Notice, and have included with this form a list be used for this purpose).	st of companies ser	nt offers of compensation (the Data Matrix form should						
SECTION I: METHOD OF DATA SUPPO	RT (Check one ma	ethod only)						
i arm using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	under the	the selective method of support (or cite-all option selective method), and have included with this form a d list of data requirements (the Data Matrix form must be						
SECTION II: GENERAL O	FFER TO PAY							
[Required if using the cite-all method or when using the cite-all option under the selection	ve method to satisf	y one or more data requirements]						
I hereby offer and agree to pay compensation, to other persons, with regard to t	he approval of this	application, to the extent required by FIFRA.						
SECTION III: CERTIF	ICATION							
I certify that this application for registration, this form for reregistration, or this application for registration, the form for reregistration, or the Data-Call-in response. In a indicated in Section I, this application is supported by all data in the Agency's files that substantially similar product, or one or more of the ingredients in this product; and (2) is requirements in effect on the date of approval of this application if the application sough uses.	addition, if the cite- (1) concern the pro a type of data that	all option or cite-all option under the selective method is perties or effects of this product or an identical or would be required to be submitted under the data						
I certify that for each exclusive use study cited in support of this registration of the written permission of the original data submitter to cite that study.	or reregistration, the	at I am the original data submitter or that I have obtained						
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) 4 and the original data submitter: (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study, and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negatiations to determine, the amount and terms of compensation, if any, to be paid for the use of the study.								
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of any product in conformity with FIFRA.								
I certify that the statements I have made on this form and all attachme knowingly false or misleading statement may be punishable by fine or imprison	nts to it are true, ment or both und	accurate, and complete. I acknowledge that any ler applicable law.						
Signature ann Mi. Illeu	9/19/13	Typed or Printed Name and Title Ann M. Tillman, Agent						

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

	DATA MA	ATRIX			
Date September 19, 2013			EPA Reg. No./File Symbol 84229-	Page of 4	
Applicant's/Registrant's Name & Add	Tide International USA, Inc. 21 Hubble Irvine, CA 92618		Product Tide Hexazinone	rechnical rechnical	
Ingredient Hexazinone (CAS No. 51	235-04-2)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Req	uirements				
830.1550	Product Identity and Composition	Volume 1	Tide International USA, Inc.	OWN	
830.1600	Description of Materials Used to Produce the Product	Volume 1	Tide International USA, Inc.	OWN	
830.1620	Description of Production Process	Volume 1	Tide International USA, Inc.	OWN	
830.1650	Description of Formulation Process				Not required ¹
830.1670	Discussion of Formation of Impurities	Volume 1	Tide International USA, Inc.	OWN	
830.1700	Preliminary Analysis	Volume 2	Tide International USA, Inc.	OWN	
830.1750	Certified Limits	Volume 1	Tide International USA, Inc.	OWN	
830.1800	Enforcement Analytical Method	Volume 1	Tide International USA, Inc.	OWN	
		Volume 2	Tide International USA, Inc.	OWN	
		Volume 3	Tide International USA, Inc.	OWN	
830.6302	Color	Volume 4	Tide International USA, Inc.	OWN	
830.6303	Physical State	Volume 5	Tide International USA, Inc.	OWN	
830.6304	Odor	Volume 6	Tide International USA, Inc.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	Volume 7	Tide International USA, Inc.	OWN	
830.6314	Oxidation/Reduction: Chemical Incompatibility	Volume 8	Tide International USA, Inc.	OWN	
Signature			Name and Title		Date
am M. Jellen		••:	Ann M. Tillman, Consultant		Sept. 19, 2013

	DATA	MATRIX			
Date September 19, 2013			EPA Reg. No./File Symbol 84229-		Page 2 of 4
Applicant's/Registrant's Name & Address Tide International USA, Inc. 21 Hubble Irvine, CA 92618		Product Tide Hexazinone Technical			
Ingredient Hexazinone (CAS No. 5	1235-04-2)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6315	Flammability	Volume 15	Tide International USA, Inc.	OWN	Waiver ²
830.6316	Explodability	Volume 15	Tide International USA, Inc.	OWN	Waiver ³
830.6317	Storage Stability	Volume 15	Tide International USA, Inc.	OWN	PRN 92-5⁴
830.6319	Miscibility				Not required ⁵
830.6320	Corrosion Characteristics	Volume 15	Tide International USA, Inc.	OWN	PRN 92-5 ⁴
830.6321	Dielectric Breakdown Voltage				Not required ⁶
830.7000	рН	Volume 9	Tide International USA, Inc.	OWN	
830.7050	UV/Visible Absorption	Volume 10	Tide International USA, Inc.	OWN	
830.7100	Viscosity	Volume 15	Tide International USA, Inc.	OWN	Waiver ⁷
830.7200	Melting Point/Melting Range	Volume 11	Tide International USA, Inc.	OWN	
830.7220	Boiling Point/Boiling Range	Volume 15			Not required ⁸
830.7300	Density/Relative Density/Bulk Density	Volume 12	Tide International USA, Inc.	OWN	
830.7370	Dissociation Constants in Water	Volume 15	Tide International USA, Inc.	PL	
830.7520	Particle Size, fiber length, and diameter distribution	Volume 15	Tide International USA, Inc.	OWN	Waiver ⁹
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	Volume 15	Tide International USA, Inc.	PL	
Signature	• •••		Name and Title	<u> </u>	Date
am M. Jeller			Ann M. Tillman, Consultant		Sept. 19, 2013

	DATA	MATRIX			
Date September 19, 2013			EPA Reg. No./File Symbol 84229-		Page 3 of 4
Applicant's/Registrant's Name & Address Tide International USA, Inc. 21 Hubble Irvine, CA 92618			Product Tide Hexazinone Technical		
Ingredient Hexazinone (CAS No. 51	235-04-2)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7560
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7560
830.7840	Water Solubility: Column Elution Method;	Volume 13	Tide International USA, Inc.	OWN	
	Shake Flask Method	Volume 14	Tide International USA, Inc.	OWN	
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure	Volume 15	Tide International USA, Inc.	PL	
870.1100	Acute Oral Toxicity: Rat	Volume 16	Tide International USA, Inc.	OWN	
870.1200	Acute Dermal Toxicity: Rat	Volume 17	Tide International USA, Inc.	OWN	
870.1300	Acute Inhalation Toxicity: Rat	Volume 18	Tide International USA, Inc.	OWN	
870.2400	Primary Eye Irritation: Rabbit	Volume 19	Tide International USA, Inc.	OWN	
870.2500	Primary Dermal Irritation	Volume 20	Tide International USA, Inc.	OWN	
870.2600	Dermal Sensitization	Volume 21	Tide International USA, Inc.	OWN	
Generic Data Requirement	ts	••••			
Tide International USA, Inc. the April 8, 2013 Data Subm	will make offers-to-pay to the following companies on hitters List for Hexazinone				
		Cite-All	Nufarm Americas Inc.	PAY	
Signature		••••	Name and Title		Date
am M. Jeller			Ann M. Tillman, Consultant		Sept. 19, 2013

		DATA MATRIX	- T-		
Date September 19, 2013			EPA Reg. No./File Symbol 84229-		Page 4 of 4
Applicant's/Registrant's Name & Address Tide International USA, Inc. 21 Hubble Irvine, CA 92618		Product Tide Hexazinone Technical			
Ingredient Hexazinone (CAS No. 51	1235-04-2)	111111			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	FMC Corp Agricultural Products Group	PAY	
		Cite-All	E. I. DuPont de Nemours and Co.	PAY	
		Cite-All	Helena Chemical Co.	PAY	
		Cite-All	Makhteshim Agan of North America, Inc.	PAY	
		Cite-All	Spray Drift Task Force	OWN	See endnote
		Cite-All	Outdoor Residential Exposure Task Force LLC	OWN	See endnote ¹
		Cite-All	Agricultural Reentry Task Force	OWN	See endnote ¹
		Cite-All	FIFRA Endangered Species Task Force LLC	PAY	
		Cite-All	Agricultural Handlers Exposure Task Force	OWN	See endnote ¹
		Cite-All	Alligare, LLC	PAY	
		Cite-All	Celsius Property B.V. Amsterdam	PAY	
Signature	•••		Name and Title		Date
am m. Jeller	•		Ann M. Tillman, Consultant		Sept. 19, 2013

Endnotes for Data Matrix for Tide Hexazinone Technical

^{830.1650 -} These data are not required for the registration of a technical product. See 830.1620 for production process information.

² 830.6315 - Tide International requests a waiver from this data requirement because Tide Hexazinone Technical is a solid and is not expected to be flammable.

³ 830.6316 - Tide International requests a waiver from this data requirement because hexazinone does not have the chemical bonds or functional groups associated with explosive chemicals.

^{4 830.6317} and 830.6320 - Per PR Notice 92-5, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Tide International USA, Inc. has initiated these studies and will submit the final reports if required when the studies are completed.

⁵ 830.6319 – This data requirement is required when the MUP is an emulsifiable liquid and to be diluted with petroleum solvents. Tide Hexazinone Technical is a technical solid that is not to be diluted with petroleum solvents. This data requirement is not applicable.

⁶ 830.6321 – These data are not required unless the product is an end-use product. Tide Hexazinone Technical is a technical grade material and this data requirement is not applicable.

⁷ 830.7100 - These data are required when the product is a liquid. Tide Hexazinone Technical is a solid. Therefore, this data requirement is not applicable to Tide Hexazinone Technical.

⁸ 830.7220 – Boiling point data are only required for liquids. Tide Hexazinone Technical is a solid. Therefore, this data requirement is not applicable to Tide Hexazinone Technical.

⁹ 830.7520 - Tide International USA Inc. requests a waiver for this data requirement for Tide Hexazibone Technical because hexazinone is not a fibrous material and is not a water-insoluble material.

¹⁰ Tide International USA, Inc. is a member in good standing with this task force.

	D.	ATA MATRIX			
Date September 19, 2013 Applicant's/Registrant's Name & Address Tide International USA, Inc. 21 Hubble Irvine, CA 92618		EPA Reg. No./File Symbol 84229-		Page of 4	
		Product Tide Hexazinone Technical			
Ingredient Hexazinone (CAS No. 51	235-04-2)	· · · -	-		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Tide International USA, Inc.	OWN	
			Tide International USA, Inc.	OWN	
			Tide International USA, Inc.	OWN	
					Not required ¹
			Tide International USA, Inc.	OWN	
			Tide International USA, Inc.	OWN	
			Tide International USA, Inc.	OWN	
			Tide International USA, Inc.	OWN	
			Tide International USA, Inc.	OWN	
			Tide International USA, Inc.	OWN	
			Tide International USA, Inc.	OWN	
			Tide International USA, Inc.	OWN	
			Tide International USA, Inc.	OWN	
			Tide International USA, thc.	OWN	
			Tide International USA, Inc.	OWN	
Signature Ann M. Jullen			Name and Title Ann M. Tillman, Consultant		Date Sept. 19, 2013

	D.	ATA MATRIX			
Date September 19, 2013			EPA Reg. No./File Symbol 84229-		Page 2 of 4
Applicant's/Registrant's Name & Address Tide International USA, Inc. 21 Hubble Irvine, CA 92618		Product Tide Hexazinone Technical			
Ingredient Hexazinone (CAS No. 5				· · · · · · · · · · · · · · · · · · ·	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Tide International USA, Inc.	OWN	Waiver ²
			Tide International USA, Inc.	OWN	Waiver ³
			Tide International USA, Inc.	OWN	PRN 92-5⁴
					Not required ⁵
			Tide International USA, Inc.	OWN	PRN 92-5⁴
					Not required ⁶
			Tide International USA, Inc.	OWN	
			Tide International USA, Inc.	OWN	
			Tide International USA, Inc.	OWN	Waiver ⁷
			Tide International USA, Inc.	OWN	
					Not required ⁸
			Tide International USA, Inc.	OWN	
			Tide International USA, Inc.	PL	
			Tide International USA, Inc.	OWN	Waiver ⁹
			Tide International USA, Inc.	PL	
- Bignature			Name and Title		Date
am Mille			Ann M. Tillman, Gensultant		Sept. 19, 2013

		DATA M	ATRIX			
Date September 19, 2013	•			EPA Reg. No./File Symbol 84229-		Page 3 of 4
Applicant's/Registrant's Name & Address Tide International USA, Inc. 21 Hubble Irvine, CA 92618		Product Tide Hexazinone Technical				
Ingredient Hexazinone (CAS No. 512	235-04-2)					
Guideline Reference Number	Guideline Study Name		MRID Number	Submitter	Status	Note
						See 830.7560
						See 830.7560
				Tide International USA, Inc.	OWN	
				Tide International USA, Inc.	OWN	
						See 830.7840
				Tide International USA, Inc.	PL	
				Tide International USA, Inc.	OWN	
				Tide International USA, Inc.	OWN	
				Tide International USA, Inc.	OWN	
				Tide International USA, Inc.	OWN	
				Tide International USA, Inc.	OWN	_
				Tide International USA, Inc.	OWN	
				• • • • • • • • • • • • • • • • • • • •		
				Nufarm Americas Inc.	PAY	
Signature Am M. Jullen				Name and Title Ann M. Tillman Consultant		Date Sept. 19, 201

		DATA MATRIX				
Date September 19, 2013			EPA Reg. No./File Symbol 84229-		Page 4 of 4	
Applicant's/Registrant's Name & Address Tide International USA, Inc. 21 Hubble Irvine, CA 92618		Product Tide Hexazinone Technical				
Ingredient Hexazinone (CAS No. 5	•				. ,	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
			FMC Corp Agricultural Products Group	PAY		
			E. I. DuPont de Nemours and Co.	PAY		
			Helena Chemical Co.	PAY		
			Makhteshim Agan of North America, Inc.	PAY		
			Spray Drift Task Force	OWN	See endnote ¹⁰	
			Outdoor Residential Exposure Task Force LLC	OWN	See endnote ¹⁰	
			Agricultural Reentry Task Force	OWN	See endnote ¹⁰	
			FIFRA Endangered Species Task Force LLC	PAY		
			Agricultural Handlers Exposure Task Force	OWN	See endnote ¹⁰	
			Alligare, LLO	PAY		
			Celsius Property B.V Amsterdam	PAY		
Signature Am Mi Tiller			Name and Title Ann M. Tillman, Consultant	-	Date Sept. 19, 2013	

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL					
EPA Registration #	Date Submitted to EPA	Electronic file name			
084229-xxxxx	Sept. 19, 2013	084229-xxxxx.20130919.Tide Hexazinone Technical.Label.pdf			

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature

Ann M. Tillman

am m. Jeller

Agent, Tide International USA Inc.

Sept. 19, 2013 Date

There is an ELECTRONIC LABEL for this action

You can use Acrobat to compare the e-label to the previous version (and find the changes). You can also use Acrobat to mark-up the e-label with your comments.

If e-label was submitted via

CD-ROM with paper application

then you will find e-label in

Electronic Label Library

If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the Front End.

or

If e-label was submitted via

XML E-Submission (no paper)

then you will find e-label in

Documentum

See overview of processing e-labels on other side of this sheet. If you have any questions on e-labels, please contact one of your division e-label experts:

AD.

Willie Abney

308-1689

Renae Whitaker

308-7003

Tracy Lantz

308-6415

BPPD

RD

Tom Harris

308-9423



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

September 26, 2013

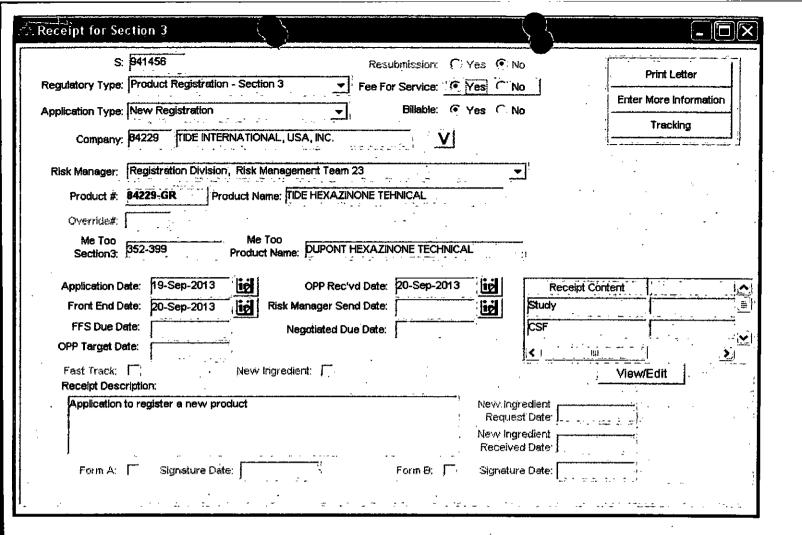
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

PYXIS REGULATORY CONSULTING, INC TIDE INTERNATIONAL, USA, INC. 4110 136TH ST. NW GIG HARBOR, WA 98332

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 20-SEP-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



21-Day Screen Completed by Contractor

21-Day Expires on 10/11/13

Jacket #<u>84339- GR</u> MRID#<u>492 199</u>

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

Steve Schaible

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only) September 2012

21 Day Screen Start Date: 9-20	13 september 2012		
Experts In-Processing Signature:	B.B.	Date 9-24-13	Fee Paid: Yes
Division management contacted on issue	s NoYes	Date	

	Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete includitype	ng pac	kage	×		
2	Confidential Statement of Formula all boxes completed, form signated (EPA Form 8570-4)	gned, a	nd	X		
2	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)				,i.e	
3	Certification with Respect to Citation of Data (EPA Form 8570-completed and signed (N/A if 100% repack)	<u>34</u>)		X		
	Certificate and data matrix consistent			X	,	
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only	 у.				
4	Formulator's Exemption Statement (EPA Form 8570-27) complesigned (N/A if source is unregistered or applicant owns the technical	eted an	d			X
	Data Matrix (EPA Form 8570-35) both internal and external copie completed and signed (N/A if 100% repack)	es (<u>PR</u>	<u>98-5</u>)	X		
_		yes	no			
5	a) Selective Method (Fee category experts use)	X_				
	b) Cite-All (Fee category experts use)				4.1	
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> (<u>Electronic labels on CD</u> are encouraged and available)	guida	nce is	X		
7	Is the data package consistent with PR Notice 86-5		-	X		

9	If applicable for conventional applications, reduced risk rationale	-	
	Required Data and/or data waivers. See Footnote C.		
	a) List study (or studies) not included with application		
10			
10			,

\boldsymbol{C}_{Δ}	-		. 40.
vu	mn	IÇU	113.

X A.T + % Comp & cotegay added

* CSF approved under Technical + impuntion.

* Data Package approved

* Jackel approved

MK10: 492199 1K 203-348-8518 * N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are strongly encouraged to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency even if a product is currently registered by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
- 2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
- 3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
- 4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

- Correct the application by, for instance, correcting the inert's identity or CAS
 number, providing documentation that the inert has been approved, or
 removing the unapproved inert from the CSF or replacing it with one that is
 approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
- 3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

- B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.
- C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

September 24, 2013 ·

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OPP Decision Number: D-483382

EPA File Symbol or Registration Number: 84229-GR Product Name: TIDE HEXAZINONE TEHNICAL

EPA Receipt Date: 20-Sep-2013 EPA Company Number: 84229

Company Name: TIDE INTERNATIONAL, USA, INC.

ANN M. TILLMAN
PYXIS REGULATORY CONSULTING, INC
TIDE INTERNATIONAL, USA, INC.
4110 136TH ST. NW
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R333

NEW PRODUCT; MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF THE ACTIVE INGREDIENT; REQUIRES SCIENCE DATA REVIEW; NEW PHYSICAL FORM; CITE-ALL OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff

Information Technology & Resources Management Division

Fee for Service



This package includes the following

- New Registration
- Amendment
- Studies? □ Fee Waiver?
- □ volpay % Reduction: ____

for Division

- OAD
- **BPPD**
- RD

Risk Mgr.

23

Receipt No.

EPA File Symbol/Reg. No.

Pin-Punch Date:

S-941456

84229-GR

9/20/2013

This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

R333

Amount Due: \$

Parent/Child Decisions:

84779-GR 84279-66

Inert Cleared for Intended Use

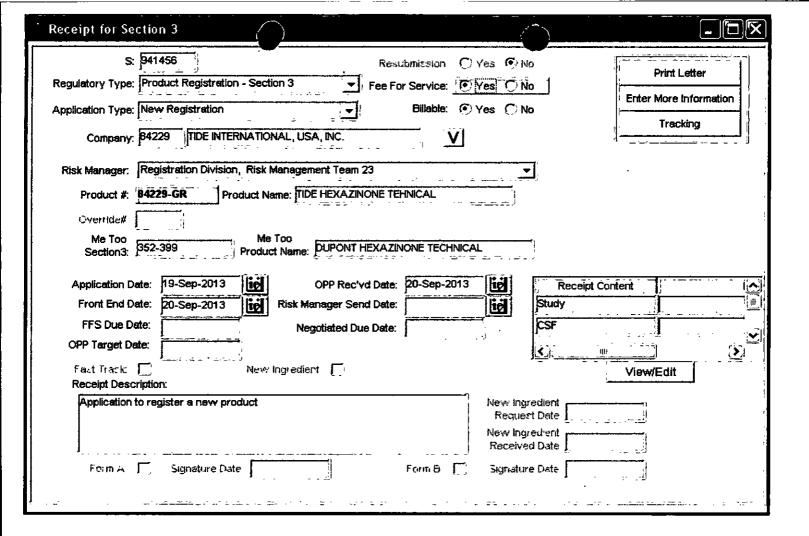
Reviewer:

Uncleared Inert in Product

Date: 9

Remarks:

GORDVO 84229-6E





4110 136th St. NW Gig Harbor, WA 98332

Phone: 253-853-7369 Fax: 253-853-5516 www.PyxisRC.com

September 19, 2013

BY COURIER DELIVERY

U.S. Bank Government Lockbox 979074 1005 Convention Plaza SL-MO-C2-GL St. Louis, MO 63197

RE.

Tide International USA, Inc.

Tide Hexazinone Technical (EPA Reg. No. 84229-

Application for New Pesticide Registration

PRIA Category R333

Sir or Madam:

On behalf of Tide International USA, Inc., we are submitting the PRIA payment for the above application for registration of Tide Hexazinone Technical (EPA Reg. No. 84229-). The certified check in the amount of \$17,993 is enclosed along with a copy of the letter submitted with the application for registration.

You may contact me at (253) 853-7369 or by email at Ann@PyxisRC.com.

Sincerely,

)

Ann M. Tillman

Enclosures

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW Gig Harbor, WA 98332 Phone: 253-853-7369

Fax: 253-853-5516 www.PywisR.C.com

September 19, 2013

OVERNIGHT DELIVERY

Kathryn V. Montague (PM 23)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Dear Ms. Montague,

RE:

Tide International USA, Inc.

Tide Hexazinone Technical (EPA Reg. No. 84229-Application for New Pesticide Registration

PRIA Category R333

On behalf of Tide International USA, Inc., we are submitting an application for registration of Tide Hexazinone Technical. This application for registration is <u>linked</u> to a secondary application (Tide Hexazinone 75 WDG). In support of this application, we submit the following documents:

- 1. Application for a New Pesticide Registration (EPA Form 8570-1)
- 2. Confidential Statement of Formula (EPA Form 8570-4) for Basic Formulation
- 3. Three (3) Copies of the Proposed Labeling
- 4. A CD containing an electronic version of the label
- 5. Certification with Respect to Label Integrity
- 6. Certification with Respect to Citation of Data (EPA Form 8570-34)
- 7. Agency Internal Use Copy of the Data Matrix
- 8. Public File Copy of the Data Matrix
- 9. Copy of PRIA payment
- 10. Letter of Authorization
- 11. Product Specific Data (3 copies of each report)

Volume 1	830.1550, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800	Tillman, A.M. and Z. Xiangfei. Product Identity and Composition. Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, Certified Limits and Enforcement Analytical Method for Tide Hexazinone Technical. Contains Confidential Business Information
Volume 2	830.1700, 830.1800	Tillman, A. M. Compilation Report: 5-Batch Analysis of Hexazinone 98% Tech and Validation of Analytical Methods, Determination of IR, UV/VIS-Absorption and Mass-Spectra. Contains Confidential Business Information
Volume 3	830.1800	Marne, S. K. Validation of Analytical Method for Hexazinone.
Volume 4	830.6302	Waghade, D. B. Determination of Colour of Hexazinone Technical.
Volume 5	830.6303	Waghade, D. B. Determination of Physical State of Hexazinone Technical.
Volume 6	830.6304	Waghade, D. B. Determination of Odour of Hexazinone Technical.

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Volume 7	830.6313	Karambelkar, N. P. Determination of Storage Stability of Hexazinone Technical to Normal and Elevated Temperature, Metals and Metal Ions.
Volume 8	830.6314	Karambelkar, N. P. Determination of Oxidizing/Reducing Properties of Hexazinone Technical.
Volume 9	830.7000	Waghade, D. B. Determination of pH of Hexazinone Technical.
Volume 10	830.7050	Marne, S. K. Determination of UV-Visible Spectrum of Hexazinone Technical.
Volume 11	830.7200	Marne, S. K. Determination of Melting Point/Melting Range of Hexazinone Technical.
Volume 12	830.7300	Waghade, D. B. Determination of Density of Hexazinone Technical
Volume 13	830.7840	Karambelkar, N. P. Determination of Solubility of Hexazinone Technical in Water.
Volume 14	830.7840	Karambelkar, N. P. Determination of Solubility of Hexazinone Technical in Organic Solvents.
Volume 15	830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7100, 830.7220 830.7370, 830.7520, 830.7550-7570, 830.7950	Tillman, A. M. Tide Hexazinone Technical: Physical and Chemical Properties and Waiver Requests.
Volume 16	OECD 425	Dhokale, C. S. Acute Oral Toxicity Study of Hexazinone Technical in Rat.
Volume 17	OECD 402	Dhokale, C. S. Acute Dermal Toxicity Study of Hexazinone Technical in Rat.
Volume 18	OECD 403	Patil, J. J. Acute Inhalation Toxicity Study of Hexazinone Technical in Rat.
Volume 19	OECD 405	Kale, M. B. Acute Eye Irritation/Corrosion Test of Hexazinone Technical in Rabbit.
Volume 20	OECD 404	Kale, M. B. Acute Dermal Irritation/Corrosion Test of Hexazinone Technical in Rabbit.
Volume 21	OECD 406	Pachpute, P. R. Skin Sensitization Study (Buehler Test) of Hexazinone Technical in Guinea Pigs.

Tide International USA, Inc. is using the cite-all method of data support. As per EPA's interpretations of 40 CFR Parts 152.86(b)(2)(i) and 152.93(b)(2)(i), Tide International USA, Inc. submitted notices of intent to apply and offers to pay to all companies on the April 8, 2013 Data Submitter's List. This action falls under PRIA category R333 (52: New manufacturing-use product). The fee for this action is \$17,993 and has been paid.

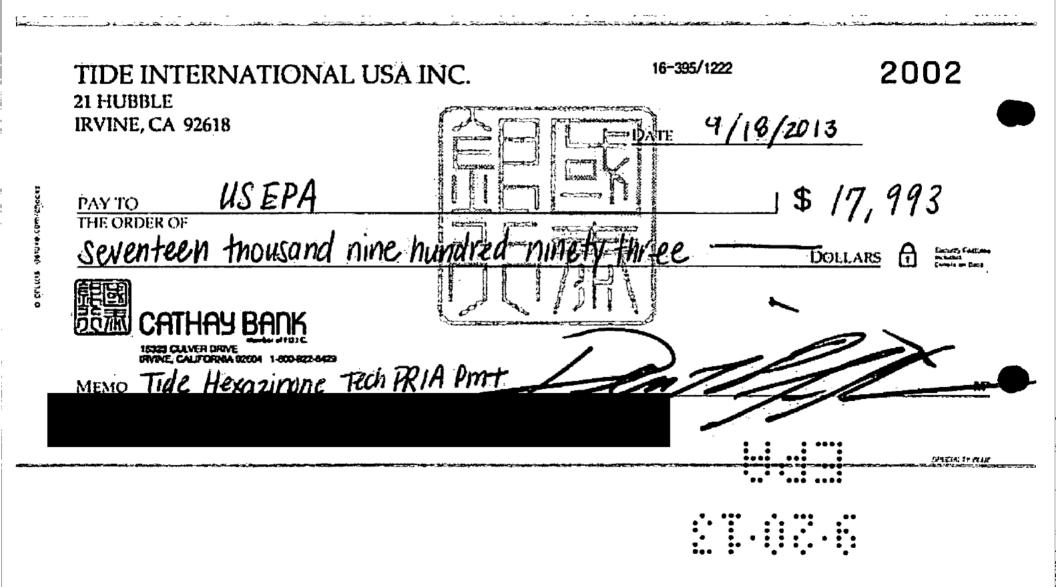
Please contact me ((253) 853-7369, Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,

Ann M. Tillman

Enclosures

Commercial/financial information may be entitled to confidential treatment



Completion of 21-Day Content Screen

PM- 23

EPA Reg. #(File Symbol) 84229 GR

Decision # D 483382

Data package delivered to you on ________. (date)

Jacket/Mini-jacket will be transferred to you today. (Pick up from Document Center)

Thank you, 🦈

Registration Division's 21-Day Content Team

Memorandum

Date: 9/27/13

To: PM 23, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: If fully accepted submission

☐ partially accepted submission

☐ rejected submission

